

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

AMY W. SCHULMAN
DLA PIPER LLP
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 335-4500
Facsimile: (212) 335-4501
amy.schulman@dlapiper.com

STUART M. GORDON (SBN: 037477)
GORDON & REES LLP
Embarcadero Center West
275 Battery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 986-5900
Facsimile: (415) 986-8054
sgordon@gordonrees.com

MICHAEL C. ZELLERS (SBN: 146904)
TUCKER ELLIS & WEST LLP
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com

Attorneys for Defendants
PFIZER INC., PHARMACIA CORPORATION,
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

LORRAINE MAHER,
Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
and G.D. SEARLE LLC, (FKA G.D. SEARLE &
CO.),

Defendants.

) MDL Docket No. 1699
)
) CASE NO. 3:07-cv-02692-CRB
)
) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**
)
) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
3 ("Searle"), (collectively "Defendants") and file this Answer to Plaintiff's Complaint
4 ("Complaint"), and would respectfully show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
8 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted
9 generally. Defendants may seek leave to amend this Answer when discovery reveals the
10 specific time periods in which Plaintiff was prescribed and used Celebrex®.

11 **II.**

12 **ANSWER**

13 Answering the unnumbered paragraph preceding Paragraph 1 of the Complaint,
14 Defendants admit that Plaintiff brought this civil action seeking monetary damages, but deny
15 that Plaintiff is entitled to any relief or damages. Defendants admit that, during certain periods
16 of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
17 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
18 with their approval by the FDA. Defendants admit that, during certain periods of time,
19 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
20 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
21 providers who are by law authorized to prescribe drugs in accordance with their approval by the
22 FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
27 and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Parties

1. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

2. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that, as the result of a merger in April 2003, Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States, including Hawaii, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Celebrex® in the United States, including Hawaii and California, to be prescribed by healthcare

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 providers who are by law authorized to prescribe drugs in accordance with their approval by the
2 FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

3 5. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
4 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
5 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
6 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
7 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
8 Celebrex® in the United States to be prescribed by healthcare providers who are by law
9 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
10 that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle
11 and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this
12 paragraph of the Complaint.

13 6. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
14 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
15 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
16 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
17 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
18 Celebrex® in the United States to be prescribed by healthcare providers who are by law
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state
20 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
21 prescribing information. Defendants state that the potential effects of Celebrex® were and are
22 adequately described in its FDA-approved prescribing information, which was at all times
23 adequate and comported with applicable standards of care and law. Defendants deny any
24 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

25 7. Defendants state that the allegations in this paragraph of the Complaint regarding
26 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
27 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
28 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Jurisdiction and Venue

8. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiff claims that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of interests and costs.

9. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny committing a tort in the State of New York or the State of California and deny the remaining allegations in this paragraph of the Complaint.

10. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States, including Hawaii and California, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pfizer, Pharmacia, and Searle are registered to and do business in the States of Hawaii and California. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny committing a tort in the States of Hawaii, New York, or California and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Interdistrict Assignment

11. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants

1 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
2 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
3 Panel on Multidistrict Litigation on September 6, 2005.

4 **Response to Factual Allegations**

5 12. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
8 paragraph of the Complaint.

9 13. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical
11 condition or whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state
12 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
13 prescribing information. Defendants state that the potential effects of Celebrex® were and are
14 adequately described in its FDA-approved prescribing information, which was at all times
15 adequate and comported with applicable standards of care and law. Defendants deny that
16 Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this
17 paragraph of the Complaint.

18 14. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Celebrex® were and are adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny the remaining allegations in this
25 paragraph of the Complaint.

26 15. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
28 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 effective when used in accordance with its FDA-approved prescribing information. Defendants
2 state that the potential effects of Celebrex® were and are adequately described in its FDA-
3 approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
5 Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this
6 paragraph of the Complaint.

7 16. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,
10 Celebrex® was expected to reach users and consumers without substantial change from the
11 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

12 16. Answering the second Paragraph 16 of the Complaint, Defendants are without
13 knowledge or information sufficient to form a belief as to the truth of the allegations in this
14 paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny
15 the same. Defendants state that Celebrex® was and is safe and effective when used in
16 accordance with its FDA-approved prescribing information. Defendants state that the potential
17 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
18 information, which was at all times adequate and comported with applicable standards of care
19 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
20 paragraph of the Complaint.

21 17. Defendants state that the allegations in this paragraph of the Complaint regarding
22 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no
23 response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times,
24 referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants deny the
25 remaining allegations in this paragraph of the Complaint.

26 18. Defendants state that the allegations in this paragraph of the Complaint are not directed
27 towards Defendants and, therefore, no response is required. To the extent that a response is
28 deemed required, Defendants state that Plaintiff fails to provide the proper context for the

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

19. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

20. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

21. Plaintiff's Complaint omits Paragraph Number 21.

22. Defendants state that the allegations in this paragraph of the Complaint regarding "other pharmaceutical companies" are not directed towards Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Plaintiff fails to provide the proper context for the remaining allegations in this paragraph and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

23. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in
2 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants
3 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
4 approved prescribing information. Defendants state that the potential effects of Celebrex®
5 were and are adequately described in its FDA-approved prescribing information, which was at
6 all times adequate and comported with applicable standards of care and law. Defendants deny
7 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

8 24. Defendants admit that Searle submitted a New Drug Application (“NDA”) for
9 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted
10 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of
11 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.
12 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to
13 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis
14 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny
15 the remaining allegations in this paragraph of the Complaint.

16 25. Defendants admit that Celebrex® was launched in February 1999. Defendants admit
17 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted
18 Celebrex® in the United States to be prescribed by healthcare providers who are by law
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
20 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
21 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
22 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
23 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe
24 and effective when used in accordance with its FDA-approved prescribing information.
25 Defendants state that the potential effects of Celebrex® were and are adequately described in its
26 FDA-approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
28 remaining allegations in this paragraph of the Complaint.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

26. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

27. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

28. Defendants state that the referenced FDA Update speaks for itself and respectfully refer the Court to the FDA Update for its actual language and text. Any attempt to characterize the FDA Update is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

29. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

30. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to characterize it is denied. Defendants admit that a Medical Officer Review dated September 20, 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 and respectfully refer the Court to the study for its actual language and text. Any attempt to
2 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
3 the Complaint.

4 31. Defendants state that the referenced article speaks for itself and respectfully refer the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

7 32. Plaintiff's Complaint omits Paragraph Number 32.

8 33. Defendants state that the referenced study speaks for itself and respectfully refer the
9 Court to the study for its actual language and text. Any attempt to characterize the study is
10 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
11 paragraph of the Complaint.

12 34. Defendants state that the Medical Officer Review speaks for itself and respectfully refer
13 the Court to the Medical Officer Review for its actual language and text. Any attempt to
14 characterize the Medical Officer Review is denied. Defendants deny any wrongful conduct and
15 deny the remaining allegations in this paragraph of the Complaint.

16 35. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee
17 hearings speak for themselves and respectfully refer the Court to the transcripts for their actual
18 language and text. Any attempt to characterize the transcripts is denied. Defendants deny any
19 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

20 36. Defendants state that the referenced articles speak for themselves and respectfully refer
21 the Court to the articles for their actual language and text. Any attempt to characterize the
22 articles is denied. Defendants state that the referenced study speaks for itself and respectfully
23 refer the Court to the study for its actual language and text. Any attempt to characterize the
24 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 37. Defendants state that the referenced article speaks for itself and respectfully refer the
26 Court to the article for its actual language and text. Any attempt to characterize the article is
27 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
28 paragraph of the Complaint.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 38. Defendants state that the referenced articles speak for themselves and respectfully refer
2 the Court to the articles for their actual language and text. Any attempt to characterize the
3 articles is denied. Defendants deny the remaining allegations in this paragraph of the
4 Complaint.

5 39. Defendants state that the referenced article speaks for itself and respectfully refer the
6 Court to the article for its actual language and text. Any attempt to characterize the article is
7 denied. Defendants state that the referenced study speaks for itself and respectfully refer the
8 Court to the study for its actual language and text. Any attempt to characterize the study is
9 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

10 40. Defendants state that the referenced Medical Officer Review speaks for itself and
11 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
12 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
13 allegations in this paragraph of the Complaint.

14 41. Plaintiff fails to provide the proper context for the allegations concerning "Public
15 Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or
16 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
17 Defendants deny the remaining allegations in this paragraph of the Complaint.

18 42. Defendants state that the referenced article speaks for itself and respectfully refer the
19 Court to the article for its actual language and text. Any attempt to characterize the article is
20 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
21 paragraph of the Complaint.

22 43. Defendants state that the referenced study speaks for itself and respectfully refer the
23 Court to the study for its actual language and text. Any attempt to characterize the study is
24 denied. Plaintiff fails to provide the proper context for the allegations concerning "Public
25 Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or
26 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
27 Defendants deny the remaining allegations in this paragraph of the Complaint.

28 44. Defendants admit that there was a clinical trial called APC. Defendants state that the

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 referenced article speaks for itself and respectfully refer the Court to the article for its actual
2 language and text. Any attempt to characterize the article is denied. Defendants deny the
3 remaining allegations in this paragraph of the Complaint.

4 45. Defendants state that the referenced article speaks for itself and respectfully refer the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Plaintiff fails to provide the proper context for the allegations concerning “Data Safety
7 Monitoring Board” in this paragraph of the Complaint. Defendants therefore lack sufficient
8 information or knowledge to form a belief as to the truth of such allegations and, therefore,
9 deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

10 46. Defendants state that the referenced article speaks for itself and respectfully refer the
11 Court to the article for its actual language and text. Any attempt to characterize the article is
12 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

13 47. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
14 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
15 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
16 Defendants deny the remaining allegations in this paragraph of the Complaint.

17 48. Defendants state that the referenced Medical Officer Review speaks for itself and
18 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
19 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
20 allegations in this paragraph of the Complaint.

21 49. Defendants admit that there was a clinical trial called PreSAP. Plaintiff fails to provide
22 the proper context for the allegations concerning “other Celebrex trials” contained in this
23 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
24 form a belief as to the truth of such allegations and, therefore, deny the same. As for the
25 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state
26 that the referenced study speaks for itself and respectfully refer the Court to the study for its
27 actual language and text. Any attempt to characterize the study is denied. Defendants deny the
28 remaining allegations in this paragraph of the Complaint.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 50. Defendants state that the referenced article speaks for itself and respectfully refer the
2 Court to the article for its actual language and text. Any attempt to characterize the article is
3 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 51. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
5 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
6 therefore lack sufficient information or knowledge to form a belief as to the truth of such
7 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for
8 themselves and respectfully refer the Court to the studies for their actual language and text.
9 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in
10 this paragraph of the Complaint.

11 52. Defendants state that the referenced Medical Officer Review speaks for itself and
12 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
13 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
14 allegations in this paragraph of the Complaint.

15 53. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint
16 are not directed toward Defendants, and therefore no response is required. To the extent that a
17 response is deemed required, Plaintiff fails to provide the proper context for the allegations in
18 this paragraph of the Complaint regarding Vioxx® in this paragraph of the Complaint.
19 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of
20 such allegations and, therefore, deny the same. Defendants state that the referenced study
21 speaks for itself and respectfully refer the Court to the study for its actual language and text.
22 Any attempt to characterize the study is denied. Defendants deny the remaining allegations in
23 this paragraph of the Complaint.

24 54. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
25 Complaint are not directed toward Defendants, and therefore no response is required. To the
26 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
27 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph
28 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the
2 referenced study speaks for itself and respectfully refer the Court to the study for its actual
3 language and text. Any attempt to characterize the study is denied. Defendants deny the
4 remaining allegations in this paragraph of the Complaint.

5 55. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
6 Complaint are not directed toward Defendants, and therefore no response is required. To the
7 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
8 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph
9 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a
10 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the
11 referenced study speaks for itself and respectfully refer the Court to the study for its actual
12 language and text. Any attempt to characterize the study is denied. Defendants state that the
13 referenced article speaks for itself and respectfully refer the Court to the article for its actual
14 language and text. Any attempt to characterize the article is denied. Defendants deny the
15 remaining allegations in this paragraph of the Complaint.

16 56. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants deny the allegations in this
18 paragraph of the Complaint.

19 57. Defendants state that the referenced article speaks for itself and respectfully refer the
20 Court to the article for its actual language and text. Any attempt to characterize the article is
21 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 58. Defendants state that allegations in this paragraph of the Complaint are not directed
23 toward Defendants, and therefore no response is required. To the extent that a response is
24 deemed required, Defendants state that the referenced article speaks for itself and respectfully
25 refer the Court to the article for its actual language and text. Any attempt to characterize the
26 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

27 59. Defendants deny the allegations in this paragraph of the Complaint.

28 60. Defendants state that Celebrex® was and is safe and effective when used in accordance

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
5 remaining allegations contained in this paragraph of the Complaint.

6 61. Defendants deny any wrongful conduct and deny the allegations contained in this
7 paragraph of the Complaint.

8 62. Defendants deny any wrongful conduct and deny the allegations contained in this
9 paragraph of the Complaint.

10 63. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct and deny the remaining allegations contained in this
15 paragraph of the Complaint.

16 64. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
23 Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of
24 the Complaint.

25 65. Defendants admit that the FDA Division of Drug Marketing, Advertising, and
26 Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and
27 November 14, 2000. Defendants state that the referenced letters speak for themselves and
28 respectfully refer the Court to the letters for their actual language and text. Any attempt to

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 characterize the letters is denied. Defendants deny the remaining allegations in this paragraph
2 of the Complaint.

3 66. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001.
4 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to
5 the letter for its actual language and text. Any attempt to characterize the letter is denied.
6 Defendants deny the remaining allegations in this paragraph of the Complaint.

7 67. Defendants state that the referenced article speaks for itself and respectfully refer the
8 Court to the article for its actual language and text. Any attempt to characterize the article is
9 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

10 68. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005.
11 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to
12 the letter for its actual language and text. Any attempt to characterize the letter is denied.
13 Defendants deny the remaining allegations in this paragraph of the Complaint.

14 69. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
19 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
20 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
21 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
22 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
23 United States to be prescribed by healthcare providers who are by law authorized to prescribe
24 drugs in accordance with their approval by the FDA. Defendants deny the remaining
25 allegations in this paragraph of the Complaint.

26 70. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
3 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
4 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
5 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
6 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
7 United States to be prescribed by healthcare providers who are by law authorized to prescribe
8 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a
9 prescription medication which is approved by the FDA for the following indications: (1) for
10 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of
11 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the
12 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps
13 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic
14 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for
15 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age
16 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this
17 paragraph of the Complaint.

18 71. Defendants state that Celebrex® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,
21 which at all times was adequate and comported with applicable standards of care and law.
22 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
23 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
24 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
25 that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

26 72. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
3 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
4 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
5 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
6 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
7 United States to be prescribed by healthcare providers who are by law authorized to prescribe
8 drugs in accordance with their approval by the FDA. Defendants deny the remaining
9 allegations in this paragraph of the Complaint.

10 73. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which at all times was adequate and comported with applicable standards of care and law.
14 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
15 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
16 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
17 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
18 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
19 United States to be prescribed by healthcare providers who are by law authorized to prescribe
20 drugs in accordance with their approval by the FDA. Defendants deny the remaining
21 allegations in this paragraph of the Complaint.

22 74. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 75. Defendants state that Celebrex® was and is safe and effective when used in accordance

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 76. Defendants deny the allegations in this paragraph of the Complaint.

7 77. Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 78. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 79. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
22 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
23 paragraph of the Complaint.

24 80. Defendants state that Celebrex® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 remaining allegations in this paragraph of the Complaint.

2 81. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Celebrex® are and were adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
7 the Complaint.

8 82. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® are and were adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
13 the study for its actual language and text. Any attempt to characterize the study is denied.
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
15 the Complaint.

16 83. Defendants deny any wrongful conduct and deny the remaining allegations in this
17 paragraph of the Complaint.

18 84. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Celebrex® are and were adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
25 remaining allegations in this paragraph of the Complaint.

26 **Response to First Cause of Action: Negligence**

27 85. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
28 Complaint as if fully set forth herein.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 86. Defendants state that this paragraph of the Complaint contains legal contentions to
2 which no response is required. To the extent that a response is deemed required, Defendants
3 admit that they had duties as are imposed by law but deny having breached such duties.
4 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
5 FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 87. Defendants state that this paragraph of the Complaint contains legal contentions to
11 which no response is required. To the extent that a response is deemed required, Defendants
12 admit that they had duties as are imposed by law but deny having breached such duties.
13 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
14 FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 88. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint, including all subparts.

27 89. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Celebrex® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
6 remaining allegations in this paragraph of the Complaint.

7 90. Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 91. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
16 effective when used in accordance with its FDA-approved prescribing information. Defendants
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-
18 approved prescribing information, which was at all times adequate and comported with
19 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
20 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
21 paragraph of the Complaint.

22 92. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical
24 conditions and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants
25 deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny
26 the remaining allegations in this paragraph of the Complaint.

27 93. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

1 94. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 **Response to Second Cause of Action: Strict Liability**

4 95. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
5 Complaint as if fully set forth herein.

6 96. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
8 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of
9 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
10 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
11 with their approval by the FDA. Defendants admit that, during certain periods of time,
12 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
13 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
14 providers who are by law authorized to prescribe drugs in accordance with their approval by the
15 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
16 consumers without substantial change from the time of sale. Defendants deny the remaining
17 allegations in this paragraph of the Complaint.

18 97. Plaintiff's Complaint omits Paragraph Number 97.

19 98. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny the remaining allegations in this paragraph of the Complaint.

24 99. Defendants state that Celebrex® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 remaining allegations in this paragraph of the Complaint.

2 100. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
7 remaining allegations in this paragraph of the Complaint, including all subparts.

8 101. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
10 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information. Defendants
12 state that the potential effects of Celebrex® were and are adequately described in its FDA-
13 approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
15 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the
16 remaining allegations in this paragraph of the Complaint.

17 102. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
22 remaining allegations in this paragraph of the Complaint.

23 103. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
25 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
26 effective when used in accordance with its FDA-approved prescribing information. Defendants
27 state that the potential effects of Celebrex® were and are adequately described in its FDA-
28 approved prescribing information, which was at all times adequate and comported with

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
2 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the
3 remaining allegations in this paragraph of the Complaint.

4 104. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 105. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
17 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
18 paragraph of the Complaint.

19 106. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 107. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
4 remaining allegations in this paragraph of the Complaint.

5 108. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 109. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
8 damage, and deny the remaining allegations in this paragraph of the Complaint.

9 110. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
10 damage, and deny the remaining allegations in this paragraph of the Complaint.

11 111. Plaintiff's Complaint omits Paragraph Number 111.

12 **Response to Third Cause of Action: Breach of Express Warranty**

13 112. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
14 Complaint as if fully set forth herein.

15 113. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
17 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
18 effective when used in accordance with its FDA-approved prescribing information. Defendants
19 state that the potential effects of Celebrex® were and are adequately described in its FDA-
20 approved prescribing information, which was at all times adequate and comported with
21 applicable standards of care and law. Defendants admit that they provided FDA-approved
22 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
23 this paragraph of the Complaint.

24 114. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
26 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
27 effective when used in accordance with its FDA-approved prescribing information. Defendants
28 state that the potential effects of Celebrex® were and are adequately described in its FDA-

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 approved prescribing information, which was at all times adequate and comported with
2 applicable standards of care and law. Defendants admit that they provided FDA-approved
3 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and
4 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

5 115. Defendants admit that they provided FDA-approved prescribing information regarding
6 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this
7 paragraph of the Complaint.

8 116. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 117. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
19 the Complaint.

20 118. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
22 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants admit that they provided FDA-approved prescribing information regarding
26 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

27 119. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

1 120. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 121. Plaintiff's Complaint omits Paragraph Number 121.

4 122. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 **Response to Fourth Cause of Action: Breach of Implied Warranty**

7 123. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
8 Complaint as if fully set forth herein.

9 124. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
10 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
11 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
12 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
13 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
14 Celebrex® in the United States to be prescribed by healthcare providers who are by law
15 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
16 the remaining allegations in this paragraph of the Complaint.

17 125. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants admit that they provided FDA-approved prescribing information regarding
22 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

23 126. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny the remaining allegations in this paragraph of the Complaint.

28 127. Defendants state that this paragraph of the Complaint contains legal contentions to

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 which no response is required. To the extent that a response is deemed required, Defendants
2 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
3 approved prescribing information. Defendants state that the potential effects of Celebrex®
4 were and are adequately described in its FDA-approved prescribing information, which was at
5 all times adequate and comported with applicable standards of care and law. Defendants deny
6 any wrongful conduct, deny that they breached any warranty, and deny the remaining
7 allegations in this paragraph of the Complaint.

8 128. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
10 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a prescription
11 medication which is approved by the FDA for the following indications: (1) for relief of the
12 signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid
13 arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of
14 primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
15 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance
16 surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the
17 signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older.
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 129. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants admit that they provided FDA-approved
26 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
27 this paragraph of the Complaint.

28 130. Defendants are without knowledge or information sufficient to form a belief as to the

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

131. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that they breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

132. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

133. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

134. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment

135. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

136. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
2 the Complaint.

3 137. Plaintiff's Complaint omits Paragraph Number 137.

4 138. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint, including all subparts.

10 139. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
15 the Complaint.

16 140. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
23 Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this
24 paragraph of the Complaint.

25 141. Defendants state that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
2 the Complaint.

3 142. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
5 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
6 effective when used in accordance with its FDA-approved prescribing information. Defendants
7 state that the potential effects of Celebrex® were and are adequately described in its FDA-
8 approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
10 remaining allegations in this paragraph of the Complaint.

11 143. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
13 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
18 remaining allegations in this paragraph of the Complaint.

19 144. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint.

27 145. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Celebrex® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
6 remaining allegations in this paragraph of the Complaint.

7 146. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
14 remaining allegations in this paragraph of the Complaint.

15 147. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
17 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
18 effective when used in accordance with its FDA-approved prescribing information. Defendants
19 state that the potential effects of Celebrex® were and are adequately described in its FDA-
20 approved prescribing information, which was at all times adequate and comported with
21 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
22 remaining allegations in this paragraph of the Complaint.

23 148. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 149. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
26 damage, and deny the remaining allegations in this paragraph of the Complaint.

27 150. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Unjust Enrichment

151. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

152. Plaintiff's Complaint omits Paragraph Number 152.

153. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

154. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

155. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

156. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

1 157. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
3 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
4 effective when used in accordance with its FDA-approved prescribing information. Defendants
5 state that the potential effects of Celebrex® were and are adequately described in its FDA-
6 approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
8 remaining allegations in this paragraph of the Complaint.

9 158. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
10 damage, and deny the remaining allegations in this paragraph of the Complaint.

11 **Response to Seventh Cause of Action:**

12 **State Consumer Fraud and Deceptive Trade Practices Act**

13 158. Answering the second Paragraph 158 of the Complaint, Defendants incorporate by
14 reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

15 159. Plaintiff's Complaint omits Paragraph Number 159.

16 160. Defendants state that this paragraph of the Complaint contains legal contentions to
17 which no response is required. To the extent that a response is deemed required, Defendants
18 admit that they had duties as are imposed by law but deny having breached such duties.
19 Defendants deny the remaining allegations in this paragraph of the Complaint.

20 161. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the
22 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 162. Defendants are without knowledge or information sufficient to form a belief as to the

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the
2 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
7 and deny the remaining allegations in this paragraph of the Complaint.

8 163. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the
10 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 164. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the
13 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 165. Defendants state that this paragraph of the Complaint contains legal contentions to
20 which no response is required. To the extent that a response is deemed required, Defendants
21 deny any wrongful conduct and deny the remaining allegations in this paragraph of the
22 Complaint.

23 166. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 167. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
26 damage, and deny the remaining allegations in this paragraph of the Complaint.

27 168. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

1 169. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 170. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
4 damage, and deny the remaining allegations in this paragraph of the Complaint.

5 **Response to Eighth Cause of Action: State Suppliers Liability Statute**

6 171. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
7 Complaint as if fully set forth herein.

8 172. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
10 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of
11 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
12 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
13 with their approval by the FDA. Defendants admit that, during certain periods of time,
14 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
15 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
16 providers who are by law authorized to prescribe drugs in accordance with their approval by the
17 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
18 consumers without substantial change from the time of sale. Defendants deny the remaining
19 allegations in this paragraph of the Complaint.

20 173. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably
25 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

26 174. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably
3 dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all
4 subparts.

5 175. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
12 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the
13 remaining allegations in this paragraph of the Complaint.

14 176. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
19 remaining allegations in this paragraph of the Complaint.

20 177. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
22 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
23 effective when used in accordance with its FDA-approved prescribing information. Defendants
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-
25 approved prescribing information, which was at all times adequate and comported with
26 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
27 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the
28 remaining allegations in this paragraph of the Complaint.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 178. Plaintiff's Complaint omits Paragraph Number 178.

2 179. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
7 the Complaint.

8 180. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
10 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information. Defendants
12 state that the potential effects of Celebrex® were and are adequately described in its FDA-
13 approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
15 remaining allegations in this paragraph of the Complaint.

16 181. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 182. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
24 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
25 effective when used in accordance with its FDA-approved prescribing information. Defendants
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-
27 approved prescribing information, which was at all times adequate and comported with
28 applicable standards of care and law. Defendants deny any wrongful conduct and deny the

1 remaining allegations in this paragraph of the Complaint.

2 183. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 184. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 185. Defendants state that this paragraph of the Complaint contains legal contentions to
7 which no response is required. To the extent that a response is deemed required, Defendants
8 deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny
9 the remaining allegations in this paragraph of the Complaint.

10 186. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
11 damage, and deny the remaining allegations in this paragraph of the Complaint.

12 **Response to Ninth Cause of Action: Unjust Enrichment**

13 187. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
14 Complaint as if fully set forth herein.

15 188. Defendants state that this paragraph of the Complaint contains legal contentions to
16 which no response is required. To the extent that a response is deemed required, Defendants
17 admit that they had duties as are imposed by law but deny having breached such duties.
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 189. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the
21 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 190. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
6 and deny the remaining allegations in this paragraph of the Complaint.

7 191. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the
9 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

10 192. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the
12 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 193. Defendants state that this paragraph of the Complaint contains legal contentions to
19 which no response is required. To the extent that a response is deemed required, Defendants
20 deny any wrongful conduct and deny the remaining allegations in this paragraph of the
21 Complaint.

22 194. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 195. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 196. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
27 damage, and deny the remaining allegations in this paragraph of the Complaint.

28 197. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or

1 damage, and deny the remaining allegations in this paragraph of the Complaint.

2 198. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 **Response to Prayer For Relief**

5 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
6 damage, and deny the remaining allegations in paragraph of the Complaint headed “Prayer for
7 Relief,” including all subparts.

8 **III.**

9 **GENERAL DENIAL**

10 Defendants deny all allegations and/or legal conclusions set forth in Plaintiff’s
11 Complaint that have not been previously admitted, denied, or explained.

12 **IV.**

13 **AFFIRMATIVE DEFENSES**

14 Defendants reserve the right to rely upon any of the following or additional defenses to
15 claims asserted by Plaintiff to the extent that such defenses are supported by information
16 developed through discovery or evidence at trial. Defendants affirmatively show that:

17 **First Defense**

18 1. The Complaint fails to state a claim upon which relief can be granted.

19 **Second Defense**

20 2. Celebrex® is a prescription medical product. The federal government has preempted
21 the field of law applicable to the labeling and warning of prescription medical products.
22 Defendants’ labeling and warning of Celebrex® was at all times in compliance with applicable
23 federal law. Plaintiff’s causes of action against Defendants, therefore, fail to state a claim upon
24 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
25 and violate the Supremacy Clause of the United States Constitution.

26 **Third Defense**

27 3. At all relevant times, Defendants provided proper warnings, information and
28 instructions for the drug in accordance with generally recognized and prevailing standards in

1 existence at the time.

2 **Fourth Defense**

3 4. At all relevant times, Defendants' warnings and instructions with respect to the use of
4 Celebrex® conformed to the generally recognized, reasonably available, and reliable state of
5 knowledge at the time the drug was manufactured, marketed and distributed.

6 **Fifth Defense**

7 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the
8 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

9 **Sixth Defense**

10 6. Plaintiff's action is barred by the statute of repose.

11 **Seventh Defense**

12 7. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily
13 negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by
14 Plaintiff should be diminished accordingly.

15 **Eighth Defense**

16 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or
17 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
18 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
19 liable in any way.

20 **Ninth Defense**

21 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
22 intervening causes for which Defendants cannot be liable.

23 **Tenth Defense**

24 10. Any injuries or expenses incurred by Plaintiff were not caused by Celebrex®, but were
25 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act
26 of God.

27 **Eleventh Defense**

28 11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff’s alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiff’s alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff’s alleged injuries/damages, if any, were the result of preexisting or subsequent

1 conditions unrelated to Celebrex®.

2 **Nineteenth Defense**

3 19. Plaintiff knew or should have known of any risk associated with Celebrex®; therefore,
4 the doctrine of assumption of the risk bars or diminishes any recovery.

5 **Twentieth Defense**

6 20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are
7 preempted in accordance with the Supremacy Clause of the United States Constitution and by
8 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

9 **Twenty-first Defense**

10 21. Plaintiff's claims are barred in whole or in part under the applicable state law because
11 the subject pharmaceutical product at issue was subject to and received pre-market approval by
12 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

13 **Twenty-second Defense**

14 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
15 Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,
16 and Plaintiff's causes of action are preempted.

17 **Twenty-third Defense**

18 23. Plaintiff's claims are barred in whole or in part by the deference given to the primary
19 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
20 issue under applicable federal laws, regulations, and rules.

21 **Twenty-fourth Defense**

22 24. Plaintiff's claims are barred in whole or in part because there is no private right of
23 action concerning matters regulated by the Food and Drug Administration under applicable
24 federal laws, regulations, and rules.

25 **Twenty-fifth Defense**

26 25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate
27 "direction or warnings" as to the use of the subject pharmaceutical product within the meaning
28 of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of New York and California, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of New York and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages;

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

(3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity

1 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

2 **Fifty-fifth Defense**

3 55. Defendants state on information and belief that the Complaint and each purported cause
4 of action contained therein is barred by the statutes of limitations contained in California Code
5 of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation
6 as may apply.

7 **Fifty-sixth Defense**

8 56. Defendants state on information and belief that any injuries, losses, or damages suffered
9 by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable
10 conduct of persons or entities other than Defendants. Therefore, Plaintiff's recovery against
11 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

12 **Fifty-seventh Defense**

13 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of
14 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil
15 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
16 damages is also barred under California Civil Code § 3294(b).

17 **Fifty-eighth Defense**

18 58. In the event Plaintiff recovers a verdict or judgment against Defendants, then said
19 verdict or judgment must be reduced pursuant to CPLR 4545(c), and/or other applicable State
20 or Commonwealth statutes, by those amounts which have, or will, with reasonable certainty,
21 replace or indemnify Plaintiff, in whole or in part, for any past or future claimed medical
22 expenses or other such economic loss, paid from any collateral source such as insurance, social
23 security, workers' compensation or employee benefit programs.

24 **Fifty-ninth Defense**

25 59. In accordance with CPLR 1601 et seq., and/or other applicable State or Commonwealth
26 statutes, the liability of Defendants, if any, to Plaintiff for non-economic loss is limited to its
27 equitable share, determined in accordance with the relative culpability of all persons or entities
28 contributing to the total liability for non-economic loss, including named parties and others over

whom Plaintiff could have obtained personal jurisdiction with due diligence.

Sixtieth Defense

60. In accordance with General Obligations Law 15-108, if Plaintiff executes a release or a covenant not to sue for a tortfeasor in this action, Plaintiff's damage claim against Defendants is reduced to the extent of any amount stipulated by the release or covenant, or in the amount of consideration paid for it, or in the amount of the released tortfeasor's equitable share of the damages under CPLR 1401 et seq., whichever is greatest.

Sixty-first Defense

61. The conduct of Defendants and all activities with respect to the subject products were fair and truthful based upon the knowledge existing at the relevant time alleged in the Complaint. Therefore, Plaintiff's claims under New York Business Corporation Law § 349 are barred.

Sixty-second Defense

62. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1
2 September 19, 2007

GORDON & REES LLP

3
4 By: : _____/s/
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

5
6
7
8 September 19, 2007

TUCKER ELLIS & WEST LLP

9
10
11 By: : _____/s/
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071
Telephone: (213) 430-3400
Fax: (213) 430-3409

12
13
14
15 Attorneys for Defendants
16 PFIZER INC, PHARMACIA
CORPORATION, and G.D. SEARLE
17 LLC
18
19
20
21
22
23
24
25
26
27
28

JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

September 19, 2007

GORDON & REES LLP

By: : _____/s/
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

September 19, 2007

TUCKER ELLIS & WEST LLP

By: : _____/s/
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendants
PFIZER INC, PHARMACIA
CORPORATION, and G.D. SEARLE
LLC

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111